

1.0 Description of the Service

Home tocolytic infusion therapy utilizes a low-dose subcutaneous infusion of a tocolytic agent as a means to prevent preterm labor in pregnant women.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid recipients may have service restrictions due to their eligibility category that would make them ineligible for this service.

2.2 Recipients with Medicaid for Pregnant Women Coverage

Tocolytic infusion therapy is covered for recipients with Medicaid for Pregnant Women (MPW) (pink Medicaid identification card).

2.3 Special Provisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. §1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at <http://www.dhhs.state.nc.us/dma/prov.htm>.

3.0 When the Service Is Covered

3.1 General Criteria

Medicaid covers home tocolytic infusion therapy when all of the requirements listed below and in **Section 3.2** are met:

- a. The procedure is medically necessary.
- b. The procedure is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs.
- c. The procedure can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide.
- d. The procedure is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker or the provider.

- e. The recipient has direct access in the home to functional telephone service for necessary contact with the provider agency, has the ability to communicate with a nurse trained in tocolytic infusion therapy or an obstetrician, is a suitable candidate for self administration of injectable medication, and is compliant with the treatment regimen in the home.

3.2 Medical Necessity Criteria

Each recipient's condition must be evaluated on an individual basis by the treating physician. All of the indicators listed below and in **Section 3.1** must be present for a recipient to receive home tocolytic infusion therapy.

- a. The recipient must be between 24 and 34 weeks' gestation.
- b. The recipient must be experiencing preterm labor and must meet all of the following conditions:
 1. contractions occurring at a frequency of four in 20 minutes or eight in 60 minutes plus progressive changes in the cervix;
 2. cervical dilation of greater than one centimeter;
 3. cervical effacement of 80 percent or greater; and
 4. oral tocolytic therapy must have been tried and failed, requiring continued infusion of the drug to stop further progression of preterm labor.
- c. The recipient must be able to operate the infusion pump, care for the infusion site, and maintain the infusion therapy after receiving training.
- d. The recipient must be able to communicate by telephone with a nurse trained in tocolytic infusion therapy management and/or obstetrician.
- e. The home environment must be suitable for the administration of the infusion and include direct telephone access for communication with the infusion therapy provider.

4.0 When the Service Is Not Covered

4.1 General Criteria

Home tocolytic infusion therapy is not covered when one or more of the criteria specified below are not met:

- a. The recipient does not meet the eligibility requirements listed in **Section 2.0**.
- b. The recipient does not meet the criteria specified in **Section 3.0**.
- c. The procedure duplicates another provider's procedure.
- d. The procedure is experimental, investigational or part of a clinical trial.

4.2 Non-Covered Conditions

The N.C. Medicaid program does not cover home tocolytic infusion therapy when one or more of the conditions specified below exist. It is important to note that there may be other indications for non-coverage and that this listing is not all inclusive.

- ruptured membranes
- evidence of suspected chorioamnionitis
- indicated delivery

- undiagnosed second or third trimester bleeding
- known drug allergy to the tocolytic agent

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

All services must be prior approved by the Carolinas Center for Medical Excellence (CCME). However, if conditions warrant, the physician may order therapy to begin on an emergency basis. All of the documentation indicated in **Attachment B** must be provided to CCME within three business days to determine coverage of services. Failure to adhere to this protocol may result in an adverse decision.

- a. The provider must submit a Tocolytic Prior Approval Referral Form, DMA 3600 (**Attachment B**), to CCME that includes the following information:
 1. recipient's name, date of birth, address, telephone number, and Medicaid identification number;
 2. provider's name, address, telephone number, and Medicaid provider number;
 3. hospital name, address and telephone number and date(s) of admission and discharge, if applicable;
 4. date of last menstrual period (LMP) or estimated date of confinement (EDC) confirmed by ultrasound; and
 5. name of oral tocolytic, start and stop dates for failed oral tocolytic therapy.
- b. A documented perinatology consult is required when the ordering physician is not a perinatologist. This documentation may be noted by the perinatologist writing an order for the services.
- c. A physician (perinatologist or obstetrician) letter of medical necessity along with written orders for the service is required and, if available, a plan of care.
- d. A clinical update must be submitted to CCME every 10 business days to obtain continued authorization for the service.

5.2 Service Components

The per diem rate for the service includes all of the following:

- a. initial registered nurse (RN) assessment of maternal/fetal environmental and psychosocial factors;
- b. assessment of recipient's ability to recognize and detect signs and symptoms of preterm labor, correctly operate monitoring and infusion devices, and comply with self-care protocols/treatment regimen as defined in the plan of care;
- c. assessments conducted by a RN with high-risk obstetrical experience;
- d. additional RN assessments as ordered by the physician;
- e. additional components as ordered by the physician shall include, but not be limited to: blood pressure and pulse monitoring, assessment, weight analysis, and dietary assessment;

- f. initial nurse education of the recipient regarding preterm labor, pregnancy, care plan objectives, data collection activities and devices, and infusion pumps to be used;
- g. ongoing reinforcement of recipient regarding preterm labor and management with subcutaneous tocolytic therapy;
- h. recipient education materials related to preterm labor, tocolytics and subcutaneous infusion therapy;
- i. use of infusion pump and uterine monitoring device;
- j. use of contraction monitor;
- k. cost of tocolytic medication, delivery, and related supplies;
- l. telephonic nursing and pharmacy support 24 hours a day, 7 days a week in accordance with all applicable laws, rules and regulations, agency policy, and the staff qualifications listed in **Section 6.2**;
- m. routine clinical status reporting to the physician;
- n. daily and “as needed” data transmission to the patient service center; and
- o. routine and “as needed” contraction and vital sign data collected by the recipient, based upon changes in recipient status, symptom management and physician plan of treatment.

6.0 Providers Eligible to Bill for the Service

6.1 Eligible Providers

Home tocolytic infusion services are provided by a home care agency that:

- a. is licensed by the Division of Facility Services (DFS) and approved to provide infusion nursing services pursuant to 10A NCAC 13J, North Carolina Rules Governing Licensure of Home Care Agencies (and adopted by reference);
- b. meets the Medicaid qualifications for participation as a home infusion therapy (HIT) provider; and
- c. is currently enrolled with the N.C. Medicaid program to provide this service.

6.2 Staff Qualifications

The agency staff must be properly trained and capable of providing the needed services. The services requiring licensed personnel must be provided by staff that is currently licensed by the appropriate North Carolina licensure board.

- a. Pharmacy services must be provided by a registered pharmacist.
- b. Infusion nursing services must be provided by a RN who is trained in tocolytic infusion therapy and in assessment of maternal and fetal status and is directly employed and/or contracted by the HIT agency.
- c. The staff member cannot be the recipient's spouse, child, parent, grandparent, grandchild or sibling, or be a person with an equivalent step or in-law relationship to the recipient.
- d. The agency must make all services available 24 hours per day, 7 days per week.

7.0 Additional Requirements

The agency must provide routine contacts and reports to the referring physician at a frequency adequate for assessment of the recipient's clinical status as the pregnancy progresses and in accordance with agency policy.

8.0 Policy Implementation/Revision Information

Original Effective Date: September 1, 2006

Revision Information:

Date	Section Revised	Change

Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in Medicaid managed care programs.

A. Claim Type

Providers bill for services using the CMS-1500 claim form.

B. Diagnosis Codes That Support Medical Necessity

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

Code	Modifier	Description
S9349	UA	Home infusion therapy, tocolytic infusion therapy

The code is billed as a daily charge and paid at a per diem rate. The UA modifier must be appended to the HCPCS code to indicate that all charges are combined.

1. The service requires prior approval (refer to **Section 5.1**).
2. The per diem for home tocolytic infusion therapy includes the initial on-site nursing assessment and additional obstetrical nursing assessments as ordered by the physician. Refer to **Section 5.2** for a list of service components.

D. Reimbursement Rate

Providers must bill usual and customary charges. The service is reimbursed on a per diem rate that includes equipment, supplies, and services to administer the drug.

Attachment B: North Carolina Department of Health and Human Services - Division of Medical Assistance

TOCOLYTIC PRIOR APPROVAL REQUEST FORM

Fax to The Carolinas Center for Medical Excellence (CCME) at (919) 380-9457.

For Prior Approval questions, contact CCME at (800) 682-2650.

☐ **Initial Request**

Initial Request: Attach **a)** copy of perinatologist order for Tocolytic therapy (or perinatology consult if ordering MD not a perinatologist); **b)** MD letter of medical necessity which includes frequency of contractions, cervical dilatation and effacement; **c)** plan of care, if available; **d)** copy of current strips; **e)** documentation of recipient home environment adequacy and recipient ability to self-perform.

Reauthorization Request: Attach **a)** clinical update from MD; **b)** nurse's notes from previous approval period; **c)** documentation supporting infusion therapy administration during previous approval period (start/stop dates, dosage, etc.); **d)** current strips.

☐ **Re-authorization Request**

Requested Tocolytic Dates of Service:

Initial Start Date _____

Initial End Date _____

Re-Auth Start Date _____

Re-Auth End Date _____

Recipient Information

Name _____ Date of Birth _____

Address _____ City _____ Zip Code _____

Home Telephone # _____

MID# _____

Caregiver Information

Name _____ Relationship _____

Address _____ Daytime Phone # _____

Physician Information

Name _____ Office Phone # _____

Address _____

Names & Phone Numbers of Other Physicians Ordering Care

Name _____ Office Phone # _____

Name _____ Office Phone # _____

Provider Agency Information

Agency Name _____ Contact Name _____

Address _____ Provider # _____

Phone # _____ Fax # _____

Medical Information

Diagnoses: _____

Gestational Age _____ EDC _____ LMP _____

Hospital Admission ☐ No ☐ Yes: Admit Date _____ Discharge Date _____

Name of Hospital for above admission _____

Address _____ Phone # _____

Describe treatment and outcome: _____

Failed Oral Tocolytic Therapy ☐ No ☐ Yes: Describe treatment, including start and stop dates

Referred By (Name) _____ Title _____

Agency _____ Phone # _____